

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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IN RE PHARMACEUTICAL INDUSTRY )  
AVERAGE WHOLESAL PRICE LITIGATION )

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) MDL No. 1456

THIS DOCUMENT RELATES TO )  
ALL ACTIONS )

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) Civil Action No. 01-CV-12257 PBS

) Judge Patti B. Saris

) Chief Magistrate Judge Marianne B. Bowler

**THE TRACK 1 DEFENDANTS' MOTION FOR LEAVE  
TO PRESENT A TUTORIAL TO THE COURT REGARDING  
PHARMACEUTICAL PRICING AND REIMBURSEMENT**

On December 17, 2004, at 2:00 in the afternoon, the Court will hear argument on plaintiffs' motion for class certification. On that day, plaintiffs will ask the Court to certify nationwide classes of companies and individuals that paid for prescription drugs on the basis of their published AWP's. Defendants will argue that a class cannot be certified.

The argument on December 17 will surely be a momentous event in these proceedings, with vast and far reaching consequences for all concerned. Almost no other decision the Court makes is more important. After all, plaintiffs' case rests on nothing less than a sweeping condemnation of the entire pharmaceutical industry. They allege that *millions* of drug purchasers have been defrauded *billions* of times in connection with nearly every drug purchased and sold in the United States. They seek court orders that reach to the root of the pricing and reimbursement system.

The decision this Court makes on class certification is supremely important to pharmaceutical consumers, payors, and sellers alike. All of these parties have an interest in ensuring that the Court's decision is based on a clear understanding of the relevant facts. The stakes could not be higher. See, e.g., In the Matter of Bridgestone/Firestone, Inc., 288 F.3d 1012, 1015-16 (7<sup>th</sup> Cir. 2002) (aggregation of large numbers of claims makes the "stakes so

large” that settlement calculus “reflects the risk of a catastrophic judgment as much as, if not more than, the actual merit of the claims.”).

Accordingly, the Track 1 defendants<sup>1</sup> hereby seek leave to present the Court with a tutorial relating to drug pricing and reimbursement. Defendants propose to present this tutorial *in advance* of the class certification argument on December 17. Defendants envision that the tutorial could be presented in two days, and that plaintiffs would be allocated one of those days to make whatever related presentations they wish.

The point of the tutorial, at least from the defendants’ perspective and, one hopes, from plaintiffs’ perspective, would be to help the Court arrive at a more complete understanding of the complex system of drug pricing and reimbursement. Defendants expect that the parties’ presentations to the Court would be as non-adversarial and informative as possible. Defendants’ proposal is predicated on the belief that a more complete understanding of how the pharmaceutical industry operates will help the Court undertake a rigorous analysis and decision on class certification, and will serve the interests of justice.

As it currently stands, Case Management Order No. 10 gives the parties several opportunities to present written and oral *argument* on whether a class should be certified. In keeping with those opportunities, plaintiffs’ motion contains vigorous advocacy, as will the defendants’ response.

While defendants believe these arguments will be important and useful, because they will help to sharpen the issues, defendants also believe that lawyers’ arguments alone will

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<sup>1</sup> The “Track 1 Defendants” are those Defendants identified as “Phase 1 fast track” Defendants in Case Management Order No. 10, entered by Judge Saris on March 25, 2004. Specifically, the Track 1 Defendants are AstraZeneca, the BMS Group (Bristol-Myers, OTN, and ApotHEcon), the GSK Group (GlaxoSmithKline, SmithKline Beecham, and Glaxo Wellcome), the Johnson & Johnson Group (J&J, Centocor, Ortho Biotech, J&J Healthcare Systems, Ortho McNeil Pharmaceuticals, Janssen Pharmaceutica Products, McNeil-PPC, and OrthoNeutrogena), the Schering-Plough Group (Schering and Warrick).

not be sufficient to the Court's purpose. A neutral tutorial, with equal time afforded to both sides, will help the Court to evaluate those arguments based upon a clear understanding of the facts relating to how drugs are marketed to various members of the putative class. It will also afford the Court a meaningful opportunity to ask questions of both sides. Thereafter, whatever decision the Court makes will be better informed. Everyone will benefit.

### **Pharmaceutical Pricing and Reimbursement**

Plaintiffs and defendants fundamentally disagree about the character of the pricing and reimbursement system for prescription pharmaceuticals. Plaintiffs see corruption and fraud wherever they look. Defendants believe they have done nothing wrong. The Court, for its part, recently observed during the oral argument on the motion to dismiss the AWP-related claims by the Commonwealth of Massachusetts, *"The more I'm learning about this, the less I know."* (Tr. at 16) (emphasis added).

The Court's sentiment is understandable. Pharmaceutical pricing and reimbursement is complex. Some drugs are sold directly to physicians, who seek reimbursement. Other drugs are never sold to physicians. Some reimbursement is paid by the Government. Other reimbursement is paid by private insurers. Some drugs are sold by the manufacturer at wholesale list prices, which are never discounted. Other drugs are sold at list price to the wholesaler, but the effective price to certain customers is then lowered by rebates paid to PBMs. Some of the savings negotiated by PBMs on behalf of their members are passed along to the PBM's customers. Other fees earned by the PBMs are retained. Some consumers have prescription drug insurance. Other consumers do not have insurance. Some of the insured consumers pay a flat co-pay amount. Other insured consumers pay a percentage of AWP. Some transaction prices are calculated "by reference to" AWP. Other transactions have nothing to do

with AWP. Some of the terms used in pricing and reimbursement are defined in a statute or regulation. Other terms (such as AWP) are not defined. Some terms have a common or plain meaning. Other terms do not. And, to make matters even more complicated, every generalization seems to have one or more exceptions.

Whatever else can be said about this system, the factors the Court must apply to determine whether to certify a class of payors under Rule 23 cannot be evaluated without a thorough understanding of how the system actually works. Do common questions predominate, as plaintiffs' will maintain, or do individual questions predominate, as defendants will maintain? Is the putative class ascertainable? Will a trial of the different payors' claims be manageable? Can the named plaintiffs adequately represent the interests of all members of the putative class? These are just a few of the issues the Court will have to face in deciding whether to certify a class.

Defendants do not mean to anticipate where the Court's analysis of the facts will lead with respect to these issues, but they are keenly interested that the Court understand the facts as thoroughly and completely as possible. Plaintiffs, if they want the Court's ruling to be based on sound information, should be equally keen that the Court understand all of the facts that bear on class certification. Both sides have a vital interest in ensuring that the Court's Rule 23 analysis is correct.

### **Potential Formats for the Proposed Tutorial**

The idea of a neutral tutorial is firmly entrenched in federal court practice. E.g., Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp.2d 69 (D. Mass. 2001); Mediacom Corp. v. Rates Technology, Inc., 4 F. Supp.2d 17 (D. Mass. 1998). Although defendants have a clear preference as between the various options, they recognize that, even if the Court agrees that

a tutorial makes sense, it might wish to structure things differently. There are any number of potential formats.

**Defendants' Preferred Format:** As noted, defendants believe that it would be appropriate to schedule a 2-day hearing in advance of the argument on December 17. They believe that the hearing should ideally be scheduled during the week of December 6 to 10.

Although defendants would prefer to proffer one or more witnesses at the hearing, they would not object to other formats. In lieu of witnesses, a speaking role could be given to counsel. The parties could present written materials in advance, or during the hearing, or not at all. If plaintiffs prefer it, they could make their presentation first. If plaintiffs prefer to follow the defendants' presentation, defendants would not object. The defendants would welcome the opportunity to respond to the Court's questions. Defendants assume that plaintiffs would welcome that opportunity as well.

**Other Formats:** The Court might want to receive presentations in some other format. If so, defendants would welcome the opportunity to present a tutorial in whatever form the Court wishes. The hearing could be shorter, or longer, or sooner, or later. It could be presented via video tape or an interactive CD-ROM. The Court could pose questions to the parties in advance, or wait until the tutorial. The important thing about the tutorial is not the format, but the opportunity it presents to the parties and the Court. Defendants stand ready to provide the information in whatever format the Court prefers.

**Conclusion**

For the reasons set forth above, the Track 1 defendants respectfully request that the Court permit the parties to present to the Court a tutorial on pharmaceutical pricing and reimbursement, whether in the defendants' preferred format or some other format of the Court's choosing.

Respectfully submitted,

**ON BEHALF OF THE TRACK 1 DEFENDANTS  
IN THE ABOVE-CAPTIONED ACTION**

/s/ Andrew D. Schau

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Dated: September 16, 2004

**CERTIFICATE OF SERVICE**

I hereby certify that on September 16, 2004, I caused a true and correct copy of The Track 1 Defendants' Motion for Leave to Present a Tutorial to the Court Regarding Pharmaceutical Pricing and Reimbursement to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/Andrew D. Schau

Andrew D. Schau